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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,940	07/18/2005	Oren Globerman	384/04315	3773
44909	7590	08/31/2009	EXAMINER	
PRTSI			HOLLM, JONATHAN A	
P.O. Box 16446			ART UNIT	PAPER NUMBER
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			08/31/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/517,940	GLOBERMAN, OREN
	Examiner	Art Unit
	JONATHAN A. HOLLM	3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 04 May 2009.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-43 and 58-70 is/are pending in the application.
 4a) Of the above claim(s) 7,20 and 65 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-6,8-19,21-43,58-64 and 66-70 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 23 December 2004 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>07/18/2005; 07/31/2008</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

1. **Claims 1-43 and new claims 58-70** are pending in the application with **claims 7, 20, and 65** being withdrawn from consideration and **claims 44-57** being cancelled by Applicant.
2. *Note to Applicant: several change of address forms have been filed by Mr. Martin Moynihan; however these forms cannot be approved as Mr. Moynihan is not an attorney of record. Proper Power of Attorney forms must be submitted and approved should it be desired that correspondence be addressed to Mr. Moynihan. Until such forms are submitted and approved, Office correspondence will be addressed to Mr. William Dippert, the current attorney of record.*

Election/Restriction

3. Applicant's election with traverse of **Species II** in the reply filed on 4 May 2009 is acknowledged. The traversal is on the ground(s) that claims 31-33, reported in the Office Action mailed 3 February 2009 as being drawn towards Species I, are actually generic. Applicant's arguments are found persuasive. Accordingly, **claims 31-33** will be examined on their merits as being generic to Species I and II.
4. Applicant's election with traverse of **Subspecies B** in the reply filed on 4 May 2009 is acknowledged. The traversal is on the ground(s) that the Subspecies B-1 and Subspecies B-2 are not mutually exclusive, since the implant may include multiple types of hinges. Applicant's arguments are found persuasive. Accordingly, the Subspecies

requirement for Subspecies B-1 and Subspecies B-2 is withdrawn and **claims 8-10** will be examined on their merits.

5. **Claims 7, 20, and new claim 65** are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species or subspecies, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4 May 2009.

Information Disclosure Statement

6. The information disclosure statements (IDS) submitted on 18 July 2005 and 31 July 2008 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner, except those items marked through with a line for the reasons below.

7. A legible copy is not provided for the following foreign patents cited in the IDS filed on 31 July 2008:

WO 2003/105695 (Globerman)

See 37 C.F.R. 1.98(a).

Drawings

8. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore the limitations: only one of the at least two extensions comprising a plurality of hinges (claim 7); and

the extensions extending axially away or axially towards the body prior to moving apart of the anchor points (claims 20-21); must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

9. **Claims 2, 4-6, and 42** are objected to because of the following informalities:

Regarding **claim 2**, the phrase “said two elongate extensions” (line 1) should read - - said at least two elongate extensions - -.

Regarding **claim 4**, the phrase “corresponding hinges a second” (line 2) should read - - corresponding hinges on a second - -.

Regarding **claim 5**, the phrase “corresponding hinges a second” (lines 2-3) should read - - corresponding hinges on a second - -.

Regarding **claim 6**, the phrase “corresponding hinges a second” (lines 2-3) should read - - corresponding hinges on a second - -.

Regarding **claim 42**, the phrase “said extension” (line 2) should read - - said extensions - -.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. **Claims 1-6, 8-19, 21-38, 58-60, and 64** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. **Claim 1** recites the limitation “the two anchor points” in line 3. It is unclear which two anchor points are being referred to since the claim requires a least two anchor points, in which there may be more than two anchor points. **Claims 2-6, 8-19, 21-38, 58-60, and 64** are rejected as being dependent upon rejected claim 1.

13. **Claims 3-6** recite the limitation "said one elongate extension" in lines 1 and/or 2 of the respective claim. There is insufficient antecedent basis for this limitation in the claim.

14. **Claim 3** recites the limitation "the other, coupled, extension" in line 2. There is insufficient antecedent basis for this limitation in the claim.

15. **Claims 8-9 and 26** recite the limitation "said plurality of hinges" in lines 1-2 of the respective claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 10 is rejected as being dependent upon rejected claim 9.

16. **Claim 30** recites the limitation "comprising a plurality of extensions such that said plurality of extensions define a flared section for said stent" in line 1. It is unclear whether this "plurality of extensions" is included with the "at least two elongate extensions" (as required by claim 1, line 4) or are provided in addition thereto. For examination purposes, the claim shall be read - - wherein the at least two elongate extensions define a flared section for said stent - -.

17. **Claims 31-36** recite the limitation "said flaring" in line 1 of the respective claim. There is insufficient antecedent basis for this limitation in the claim. **Claim 59** is rejected as being dependent upon rejected claim 34.

18. **Claim 37** recites the limitation "said stent" in line 1. There is insufficient antecedent basis for this limitation in the claim. **Claim 38** is rejected as being dependent upon rejected claim 37.

Claim Rejections - 35 USC § 102

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

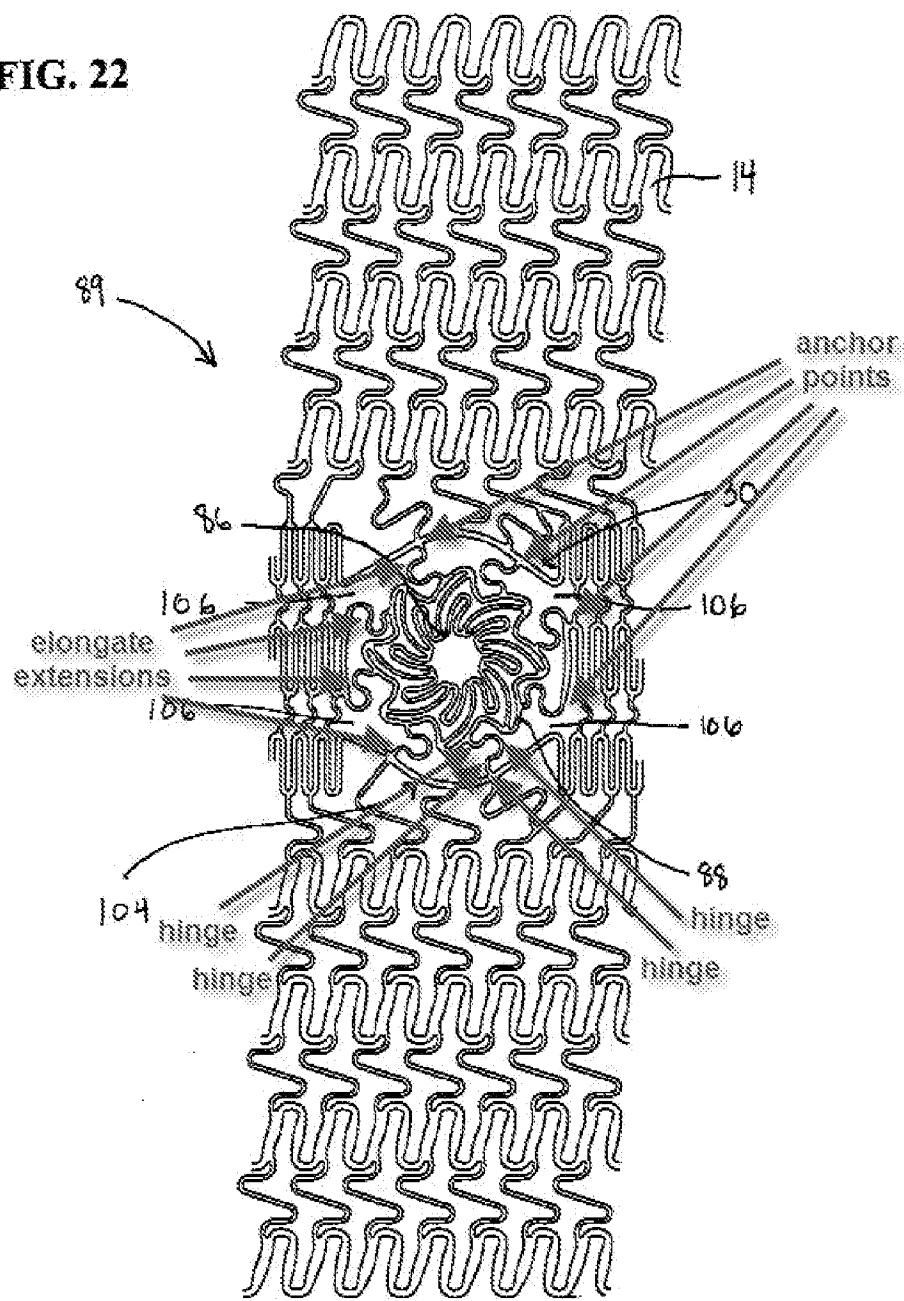
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

20. **Claims 1-6, 8-16, 21-38, 58-60, and 64** are rejected under 35 U.S.C. 102(b) as being anticipated by Davidson et al (US Patent Application Publication Number 2004/0138737).

Davidson et al disclose a deformable medical implant comprising a body (14) defining at least two anchor points and being adapted to be deformed so that two anchor points are moved relative to each other, at least two elongate extensions fixed to an anchor point, a bridge (88) coupling at least two of the extensions together, and at least two hinges defined on at least one of the extensions wherein two of said at least two hinges have different preferred bending directions (see annotated figure 22 below; paragraphs 0061-0066);

FIG. 22



wherein hinges of one extension are a mirror of hinges on another, coupled extension (i.e., hinges opposite each other with respect to opening (30)); wherein the hinges of one extension have different axial locations, bending directions, and resistances to

bending than corresponding hinges on another, coupled extension; wherein at least one of the hinges has a preferred bending direction in a device plane of the body (e.g., hinges between the anchor points and the bridge) and at least one of the hinges has a preferred bending direction perpendicular to the body (e.g., hinges at the anchor points); wherein the hinges are arranged to cooperate with the bridge to bend the extensions in a direction that includes a component perpendicular to a device plane of the body with the hinges being arranged to bend at least one of the extensions at at least two points in different directions and the hinges being arranged to bend the extensions at least 90 degrees away from the device plane of the body (see figure 21); the extensions being capable of extending axially towards said body prior to moving apart of the anchor points; the bridge being defined at the end of the extensions, being deformable, and being more resistant to bending than the hinges; the hinges being plastically deformable; the at least two hinges comprising at least three hinges on a single extension; the body being cylindrical; the implant being a mesh stent adapted for implanting in a blood vessel wherein the extensions face each other across an aperture in the stent to define a mesh flared section being symmetric about an axis that is at an angle to an axis of the stent, comprising a coupling (104) between different extensions compensating for an the angle of the flared section, being defined on a side of the stent, being generally cylindrical, and wherein the axis of the flared section may be generally perpendicular to an axis of the stent; and the hinges being parts of struts of the implant.

21. **Claims 39-43, 61, and 63** is/are rejected under 35 U.S.C. 102(b) as being anticipated by Vargas et al (US Patent Number 6,428,550).

Vargas et al disclose a method for distorting a medical implant structure having two extensions coupled at a point thereof comprising changing the relative position of two points on the extensions that are distanced from the coupling point and transforming, using a plurality of pre-defined hinges, tension forces applied by the changing into forces that bend the structure in a plane outside of a plane defined by the changing and by at least a planar portion of the extensions (see figures 1-14; column 4, line 53 – column 5, line 9); the changing being applied by radially expanding the cylindrical structure; the transforming comprising flaring out extensions including a change in angle to more than 50 degrees relative to an axis of the cylinder; two extensions facing each other; and the transforming comprising deforming parts of the extensions and not deforming other parts of the extensions.

22. **Claims 66-69** are rejected under 35 U.S.C. 102(b) as being anticipated by Davidson et al (US Patent Application Publication Number 2004/0138737).

Davidson et al discloses a stent (79) comprising an expandable cylindrical body, an aperture (30) defined in a side of the body and designed for allowing passage to a side branch, and at least two extensions (92) mounted adjacent said aperture and configured to be extended away from the body by an expansion of the body (see figures 19-21; paragraphs 0061-0065); the extensions being connected by a bridge (88) that is deformable and interconnects portions of the extensions not in a plane of the cylindrical

body (see figure 21); and the extensions being on opposing sides of the aperture (see figure 20).

Claim Rejections - 35 USC § 103

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

24. **Claims 17-19** are rejected under 35 U.S.C. 103(a) as being unpatentable over Davidson et al (US Patent Application Publication Number 2004/0138737) in view of Vargas et al (US Patent Number 6,428,550).

The device of Davidson et al is not explicitly disclosed with the hinges comprising cuts, weakenings, or bores in the extension. Vargas et al teach hinges comprising cuts, weakenings, or bores in an extension (see figure 13). It would have been obvious for a person having ordinary skill in the art at the time of the invention to modify the device of Davidson et al to have the hinges comprise cuts, weakenings, or bores in the extension in view of Vargas et al, since Vargas et al teach that such configurations are effective forms of hinges in an extension (column 8, lines 10-21).

25. **Claims 39-43 and 61-63** are rejected under 35 U.S.C. 103(a) as being unpatentable over Davidson et al (US Patent Application Publication Number 2004/0138737) in view of Vargas et al (US Patent Number 6,428,550).

Davidson et al disclose a method of distorting a medical implant structure having two extensions coupled at a point thereof comprising changing the relative position of two points on the extensions distance from the coupling point and transforming tension forces applied by said changing into forces that bend said structure in a plane outside of a plane defined by said changing and by at least a planar portion of the extensions (see paragraph 0065).

The method of Davidson et al is not disclosed with said transforming being done by using a plurality of pre-defined hinges. Vargas et al teach transforming tensioning forces applied by a changing of relative position of two points using a plurality of pre-defined hinges (see figures 3-4; column 4, line 53 – column 5, line 9). It would have been obvious for a person having ordinary skill in the art at the time of the invention to modify the method of Davidson et al to have the transforming be done by using a plurality of pre-defined hinges in view of Vargas et al, since Vargas et al illustrate such a method as being an effective way to deliver and secure an implantable medical device.

Regarding **claims 40-41**, Davidson et al disclose the structure being cylindrical, and Vargas et al disclose the changing being applied by radially expanding a cylindrical structure.

Regarding **claims 42-43**, Davidson et al disclose transforming comprising flaring out extensions including a change in angle to more than 50 degrees relative to an axis of the cylinder.

Regarding **claim 61**, Davidson et al discloses two extensions facing each other.

Regarding **claim 62**, Davidson et al disclose the implant being a stent and the extensions being extended into a side branch of a vessel bifurcation.

Regarding **claim 63**, Vargas et al disclose the transforming comprising deforming parts of the extensions and not deforming other parts of the extensions.

26. **Claim 70** is rejected under 35 U.S.C. 103(a) as being unpatentable over Davidson et al (US Patent Application Publication Number 2004/0138737) in view of Globerman et al (US Patent Number 6,402,777).

The device of Davidson et al is not explicitly disclosed with at least one of the extensions including a radio-opaque marker that extends away from the body with the extension. Globerman et al teach a stent with a radio-opaque marker attached to and capable of moving with an extension during expansion of a stent (see figures 1, 2, and 8-9). It would have been obvious for a person having ordinary skill in the art at the time of the invention to modify the device of Davidson et al to have at least one of the extensions include a radio-opaque marker that extends away from the body with the extension in view of Globerman et al, since Globerman et al teach that such a configuration allows a stent to be viewed during a procedure in order to assure proper placement of the stent (column 2, lines 15-23).

Conclusion

27. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Stanford (US Patent Application Publication Number 2001/0032011);

Calisse (US Patent Application Publication Number 2003/0055487);

Shanley (US Patent Number 6,562,065); and

Orth et al (US Patent Number 5,591,197);

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN A. HOLLM whose telephone number is (571) 270-7529. The examiner can normally be reached on Monday - Friday 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J.A.H./

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